DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95153d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-20

March 4, 2004

Paul F. Roraff, President
American Electronic Assembly
3050 S.W. 14th Place
Boynton Beach, Florida 33426

Dear Mr. Roraff:

During an inspection of your establishment located in Boynton Beach, Florida on January 29-30, 2004, FDA Investigator Sonia M. Monges determined that your establishment is a contract manufacturer of the Asepti-Clave tabletop, steam sterilizer, which is defined as a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, and the Medical Device Reporting regulations, Title 21, CFR, Part 803. These violations cause the device you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] and misbranded within the meaning of Section 502(t)(2) [21 U.S.C. §352(t)(2)] of the Act.

The investigator noted the following violations of the QS regulation:

1. Your firm failed to establish and maintain Quality System procedures as required by 21 CFR 820.20(e). There are no established procedures covering corrective and preventive action (CAPA), production/process controls, non-conforming product and complaint handling to ensure that the manufacture of the table, steam sterilizer is conducted in conformance with the Quality System Regulation (FDA 483, Item #1).

2. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). There are no procedures addressing CAPA activities as evidenced by the lack of complaint handling procedures and procedures addressing the identification, documentation, evaluation, segregation, and disposition of non-conforming product (FDA 483, Item #2).

3. Your firm failed to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsibilities and that training is documented as required by 21 CFR 820.25(b). Personnel responsible for oversight of manufacturing operations of the Asepti-Clave table, steam sterilizers have not received Quality System Regulation training (FDA 483, Item #4).

Medical Device Reporting (MDR)

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to comply with a requirement prescribed under section 519 of the Act respecting the device as follows:

4. Your firm failed to establish and maintain written MDR procedures as required by 21 CFR 803.17 (FDA 483, Item #3).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District